



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0524; FRL-9353-9]

Trinexapac-ethyl; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the existing trinexapac-ethyl tolerance levels for wheat, forage and wheat, middlings as well as change the commodity definition for hog, kidney. Additionally the EPA proposes to establish tolerances for residues of trinexapac-ethyl in or on barley, bran; sugarcane, molasses; and wheat, bran under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before [*insert date that is 60 days after publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0524 by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *<http://www.epa.gov/dockets>*.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: *benbow.bethany@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

- iv. Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. This Proposal

EPA on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to amend the existing trinexapac-ethyl tolerances for wheat, forage from 1.5 to 1.0 parts per million (ppm) and wheat, middlings from 6.5 to 10.5 ppm, as well as change the existing commodity definition for “hog, kidney” to “hog, meat by-products” as these changes are needed to correct inadvertent typographical errors listed in the final rule tolerance table for trinexapac-ethyl that was published in the **Federal Register** on March 2, 2012 (77 FR 12740) (FRL-9337-9).

Additionally, the Agency is proposing to establish tolerances for residues of trinexapac-ethyl in or on barley, bran at 2.5 ppm; sugarcane, molasses at 2.5 ppm; and wheat, bran at 6.0 ppm based on the following:

The final rule for trinexapac-ethyl that was published in the **Federal Register** of March 2, 2012, established tolerances for trinexapac-ethyl residues on the raw agricultural commodities of barley, sugarcane and wheat; however, tolerances for certain processed commodities (barley, bran; sugarcane, molasses; and wheat, bran) were not established in that final rule. Though these processed commodity tolerances were not

proposed in the petition submitted to the Agency by the registrant, Syngenta Crop Protection, Inc., EPA determined they were needed in conjunction with establishing the raw agricultural commodity tolerances on barley, sugarcane, and wheat. The data submitted by Syngenta do support these tolerances and the tolerances were included in the Agency's last dietary and aggregate risk assessments. EPA intended to establish these processed tolerances as part of the March 2, 2012, rulemaking but they were inadvertently left out. Accordingly, EPA is now proposing these tolerances on its own initiative.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of

FFDCA section 408 and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with FFDCA section 408(b)(2), for these proposed tolerances for residues of trinexapac-ethyl. EPA's assessment of exposures and risks associated with establishing these tolerances is as follows.

In connection with the March 2, 2012 final rule for trinexapac-ethyl that established tolerances for trinexapac-ethyl residues on the raw agricultural commodities of barley, sugarcane and wheat, EPA assessed not only tolerances for these raw commodities but tolerances for the following associated processed commodities: Trinexapac-ethyl on barley, bran at 2.5 ppm; sugarcane, molasses at 2.5 ppm; and wheat, bran at 6.0 ppm in the dietary risk assessment. “Trinexapac-ethyl: Acute and Chronic Dietary Exposure and Risk Assessment for the Proposed Uses on Cereal Grains, Sugarcane and Grasses Grown for Seed” (September 13, 2011), this and other supporting documents for this proposal can be accessed at www.regulations.gov under docket ID number EPA-HQ-OPP-2010-0524. In addition, EPA assessed the risk of trinexapac-ethyl tolerances for wheat, forage and wheat, middlings at the levels of 1.0 ppm and 10.5 ppm, respectively, rather than at 1.5 ppm and 6.5 ppm as reported in the March 2, 2012 final rule. Despite how the risk assessment was conducted, EPA inadvertently left the barley bran, sugarcane molasses, and wheat bran out of the final rule and, by mistake, established the wheat forage and wheat middlings tolerances at the incorrect level. EPA

also inadvertently established a tolerance for “hog, kidney” instead of using the standard Agency commodity term of “hog, meat by-products.” EPA is proposing to correct these errors.

In March 2, 2012 rule and the risk assessment underlying the rule, EPA concluded that all risk estimates were below EPA’s level of concern. The acute dietary exposure estimate for females 13 to 49 years old will only utilize 2% of the acute population adjusted dose (aPAD), which is well below the Agency’s level of concern (100% of the aPAD). Chronic exposure to trinexapac-ethyl from food and water will utilize 6% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the population group receiving the greatest exposure. Further, trinexapac-ethyl is currently registered for uses that could result in short- and intermediate-term residential exposures for adults, and the Agency has determined the combined food, water, and adult post-application dermal exposures result in aggregate MOEs of 761 for liquid products and 601 for granular products. These MOEs are above the EPA’s level of concern for trinexapac-ethyl, a MOE of 100 or below. Finally, based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, trinexapac-ethyl is not expected to pose a cancer risk to humans.

Therefore, since aggregate risk and exposure estimates do not change as a result of these tolerance proposals, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to trinexapac-ethyl residues. Refer to the March 2, 2012 **Federal Register** document, available at <http://www.regulations.gov> for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk

assessments and the findings made in the **Federal Register** document in support of this action.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A, which utilizes high performance liquid chromatography with triple-quadruple mass spectrometry) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for trinexapac-ethyl in or on commodities associated with this action.

V. Conclusion

Tolerances are proposed for residues of trinexapac-ethyl in or on barley, bran at 2.5 ppm; sugarcane, molasses at 2.5 ppm; and wheat, bran at 6.0 ppm. The EPA is also proposing to amend the existing trinexapac-ethyl tolerances for wheat, forage from 1.5 to 1.0 ppm and wheat, middlings from 6.5 to 10.5 ppm, as well as change the existing commodity definition for “hog, kidney” to “hog, meat by-products”.

VI. Statutory and Executive Order Reviews

This proposed rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23,

1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that these proposed tolerances will not have significant negative economic impact on a substantial number of small entities.

Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For

these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 5, 2012.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.662 the table in paragraph (a) is amended by:

- i. Revising the entry for “Hog, Kidney” to read “Hog, meat-byproducts”,
- ii. Revising the tolerance levels for “Wheat, forage” and “Wheat, middlings”, and
- iii. Alphabetically adding “Barley, bran”; “Sugarcane, molasses”; and “Wheat, bran process”.

The amendments read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
Barley, bran	2.5
* * *	* * *
Hog, meat by-products	0.03
* * *	* * *
Sugarcane, molasses	2.5
Wheat, bran process	6.0
Wheat, forage	1.0
* * *	* * *
Wheat, middlings	10.5
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